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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/766,084	01/28/2004	Francis Y. Lee	C035795/0191629	2411	
Kevin C. Hoope	7590 05/16/200 er. Esa.	EXAMINER			
Bryan Cave LLP 1290 Avenue of the Americas New York, NY 10104			STROUD, JONATHAN R		
			ART UNIT	PAPER NUMBER	
				3774	
			MAIL DATE	DELIVERY MODE	
			05/16/2008	PAPER	

# Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)				
	10/766,084	LEE, FRANCIS Y.				
Office Action Summary	Examiner	Art Unit				
	JONATHAN R. STROUD	3774				
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address				
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1)⊠ Responsive to communication(s) filed on 11 Fe	ebruarv 2008.					
/ <u> </u>	action is non-final.					
<i>;</i> —	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
	closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.					
Disposition of Claims						
4)⊠ Claim(s) <u>7,8 and 10-19</u> is/are pending in the application.						
4a) Of the above claim(s) <u>15-19</u> is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>7,8 and 10-14</u> is/are rejected.						
7) Claim(s) is/are objected to.						
8) Claim(s) 15-19 are subject to restriction and/or	election requirement.					
Application Papers						
9)☐ The specification is objected to by the Examiner.						
9)  The specification is objected to by the Examiner.  10)  The drawing(s) filed on 11 February 2008 is/are: a)  accepted or b)  objected to by the Examiner.						
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Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
<u> </u>	muianitu undan 25 H.C.C. \$ 440/a)	\				
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).						
a) All b) Some * c) None of:						
1. Certified copies of the priority documents have been received.						
2. Certified copies of the priority documents have been received in Application No						
3. Copies of the certified copies of the priority documents have been received in this National Stage						
application from the International Bureau (PCT Rule 17.2(a)).						
* See the attached detailed Office action for a list of the certified copies not received.						
Attachment(s)						
1) Notice of References Cited (PTO-892)	4) Interview Summary					
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08)	Paper No(s)/Mail Da 5) Notice of Informal P					
Paper No(s)/Mail Date 6) Other:						

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### **DETAILED ACTION**

## Response to Arguments

Applicant has successfully addressed the objection to the drawings, and it is thus withdrawn.

Applicant further realized the examiner's error in intending to reject claims 1-6 via Long. For clarity and the record's sake, examiner intended to reject claims 1-6 based on Long, as the applicant has made a point to note in the previous office action.

1. Applicant's arguments, see remarks, filed Feb. 8 2008, with respect to the rejection(s) of claim(s) 1-10 under 35 U.S.C. 102 (b) have been fully considered, but are moot in light of the amendments and the new ground(s) of rejection, presented herein.

#### Election/Restrictions

1. Newly submitted claims 15-19 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: It introduces a distinct process, namely the method of inhibiting the activity or formation of osteoclasts.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 15-19 withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- 3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
- 4. Claims 7, 8 and 10-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Long 6,630,153.

Re claim 7, Long teaches a bone graft composite material which replaces diseased bone and comprises a biophosphate including Pamidronate, col. 16 II. 60-66 amongst other places in the reference, further which is inserted in a bone void created by the loss of bone, col. 1 II. 10-20. Long fails to explicitly teach a method per se, but it has been held that when a prior art device is the same device described and carries out the method under normal operation, it can be assumed the device will inherently perform the claimed process. See MPEP 2112.01.

In the instant case, Long teaches a bone graft substitute with all of the claimed features of the applicant's device, including Pamidronate, and a carrier material, as described above.

Re claims 13 and 14, applicant is reminded that using a known composition for results based on the properties of the device or material is not a novel or patentable claim. "When the claim recites using an old composition or structure and the "use" is directed to a result or property of that composition or structure, then the claim is anticipated." In re May, 574 F.2d 1082, 1090, 197 USPQ 601, 607 (CCPA 1978). In the instant case, the mere presence of the prior art material speaks to the inherency of

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treating any and all types of bone loss, and of specificying the treatment site by the associated body processes therein. Further, claims 13 and 14 merely recites a number of known causes of bone loss well-known to clinicians, and a body process associated therewith, which is clearly anticipated by the prior art col. 1 II. 10-20 and the material disclosed therein. Therefore, if deemed necessary, the office declares Official Notice as to the obviousness of the well-known claimed diseases to cause bone loss, and thereby be treated with bone substitute.

### Conclusion

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to JONATHAN R. STROUD whose telephone number is (571)270-3070. The examiner can normally be reached on Monday through Friday, 8:30 a.m. to 6 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571)272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jonathan R Stroud/ Examiner, Art Unit 3774 /Thomas J Sweet/ Primary Examiner, Art Unit 3774 Application/Control Number: 10/766,084

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